



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration; Delegation of Authority

Notice is hereby given that I have delegated to the Food and Drug Administration (FDA) Commissioner of Food and Drugs (Commissioner), the authority vested in the Secretary to issue all regulations of the FDA. This includes authority to issue regulations pursuant to the Federal Food, Drug, and Cosmetic Act (FD&C Act), applicable portions of the Public Health Service Act (PHS Act), and other authorities governing functions of the FDA. This authority may be re-delegated by the Commissioner.

On September 15, 2020, the Secretary of Health and Human Services (HHS) issued a memorandum (“September 15 Memorandum”) to the HHS Heads of Operating and Staff Divisions that reserved to the Secretary “the authority to sign and issue any rule for which notice and comment would normally be required, irrespective of whether notice and comment is waived.” The September 15 Memorandum further stated that it rescinded “any prior delegation of rulemaking authority” to the Operating Divisions, including FDA. This delegation revokes the September 15 Memorandum as it applies to FDA and reinstates any delegations to FDA rescinded by the September 15 Memorandum.

This delegation shall be exercised in accordance with the Department’s applicable policies, procedures, and guidelines. For internal Department management purposes, this delegation is subject to certain reservations of authority for the Secretary to approve FDA regulations. Specifically, the Secretary reserves the authority to approve regulations of FDA, except regulations to which sections 556 and 557 of Title 5 U.S.C. apply, which (1) establish procedural rules applicable to a general class of foods, drugs, cosmetics, medical devices, tobacco products, or other subjects of regulation; or (2) present highly significant public issues involving the quality, availability, marketability, or cost of one or more foods, drugs, cosmetics,

medical devices, tobacco products, or other subjects of regulation. The delegation does not preclude the Secretary from approving a regulation, or being notified in advance of an action, to which section 556 and 557 of Title 5 U.S.C. apply, which meets one of the above-referenced criteria. This reservation of authority is intended only to improve the internal management of the Department of Health and Human Services, and it is not intended to create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, the Department of Health and Human Services, the FDA, any Agency, officer, or employee of the United States, or any person. Regulations issued by FDA without the approval of the Secretary are to be conclusively viewed as falling outside the scope of this reservation of authority.

This delegation became effective upon the date of signature. In addition, I hereby affirm and ratify any actions taken by the Commissioner or the Commissioner's subordinates which involved the exercise of the authorities delegated herein, or substantially similar authorities, prior to the effective date of the delegation.

Dated: August 30, 2021.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

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